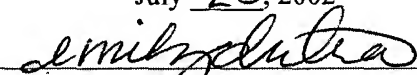


Patent Docket P1748R1E

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Frederic J. DeSavauge et al. Serial No.: 10/088,950 Filed: March 20, 2002 For: MODULATION OF T CELL DIFFERENTIATION FOR THE TREATMENT OF T HELPER CELL MEDIATED DISEASES	Group Art Unit: NOT KNOWN Examiner: NOT KNOWN <div style="text-align: right;">0 5 2002 MAIL CENTER 1600/2900</div> <div style="text-align: center;">CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on July 23, 2002  Emily Dutra</div>
--	--

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- [x] **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- [] **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.
- [] **37 CFR §1.97(d)**

Serial No.: 10/088,950
Filed: March 20, 2002

Page 2

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior related application Serial No. 09/692,504, filed October 18, 2000. The present application was filed under 35 U.S.C. §371 and contains an identical disclosure as application Serial No. 09/692,504. Moreover, both the present application and the 09/692,504 applications claim priority under 35 U.S.C. §119 to application Serial No. 60/160,542, filed on October 20, 1999.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

- ☐ given for each listed item
- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,
GENENTECH, INC.

Date: July 23, 2002

By: Atulya R. Agarwal
Atulya R. Agarwal, Ph.D.
Reg. No. 40,887
Telephone No. (650) 225-4463



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P1748R1ESerial No.
10/088,950

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Frederic deSavauge et al.Filing Date
20 Mar 2002

Group

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	4,275,149	23.06.81	Litman et al.			
	* 2	4,816,567	28.03.89	Cabilly et al.			
	* 3	5,223,409	29.06.93	Ladner et al.			
	* 4	5,403,484	04.04.95	Ladner et al.			
	* 5	5,545,806	13.08.96	Lonberg et al.			
	* 6	5,545,807	13.08.96	Surani et al.			
	* 7	5,569,825	29.10.96	Lonberg et al.			
	* 8	5,571,698	05.11.96	Ladner et al.			
	* 9	5,625,126	29.04.97	Lonberg et al.			
	*10	5,633,425	27.05.97	Lonberg et al.			
	*11	5,658,570	19.08.97	Newman et al.			
	*12	5,681,722	28.10.97	Newman et al.			
	*13	5,693,780	02.12.97	Newman et al.			
	*14	5,750,105	12.05.98	Newman et al.			
	*15	5,750,373	12.05.98	Garrard et al.			
	*16	5,756,096	26.05.98	Newman et al.			

RECEIVED
NOV 05 2002
TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	*17	WO 97/44455	27.11.97	PCT			

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

*18	Altschul et al., "Gapped BLAST and PSI-BLAST: A New Generation of Protein Database Search Programs" <u>Nucleic Acids Research</u> , 25(17):3389-3402 (1997)
*19	Bazan, J., "Structural Design and Molecular Evolution of a Cytokine Receptor Superfamily" <u>Proc. Natl. Acad. Sci. USA</u> 87:6934-6938 (1990)
*20	Boerner et al., "Production of Antigen-Specific Human Monoclonal Antibodies From In Vitro-Primed Human Splenocytes" <u>The Journal of Immunology</u> 147(1):86-95 (1991)
*21	Bolton, C., "Recent Advances in the Pharmacological Control of Experimental Allergic Encephalomyelitis (EAE) and the Implications for Multiple Sclerosis Treatment." <u>Multiple Sclerosis</u> , 1:143-149 (1995)
*22	Carter et al., "Improved Oligonucleotide Site-Directed Mutagenesis Using M13 Vectors" <u>Nucl. Acids Res.</u> 13(12):4431-4443 (June 25, 1985)
*23	Chambers and Allison., "Co-Stimulation in T Cell Responses." <u>Current Opinion in Immunology</u> , 9(3):396-404 (Jun 1997)
*24	Clackson et al., "Making Antibody Fragments Using Phage Display Libraries" <u>Nature</u> 352:624-628 (1991)
*25	Cole et al., "The EBV-Hybridoma Technique and Its Application to Human Lung Cancer" <u>Monoclonal Antibodies and Cancer Therapy</u> , New York:Alan R. Liss, Inc. pps. 77-96 (1985)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1748R1E

Serial No.

10/088,950

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Frederic deSavauge et al.

Filing Date

20 Mar 2002

Group

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- | | |
|-----|---|
| *26 | Constant, S.L. et al., "Induction of Th1 and Th2 CD4+ T Cell Responses: The alternative approaches" <u>Annual Review of Immunology</u> 15:297-322 (1997) |
| *27 | Cosman, D., "The Hematopoietin Receptor Superfamily" <u>Cytokine</u> 5(2):95-106 (Mar 1993) |
| *28 | Finn and Lotze., "Introduction: Third Keystone Symposium on Cellular Immunology and the Immunotherapy of Cancer." <u>Journal of Immunotherapy</u> , 21(2):114-118 (Mar 1998) |
| *29 | Fishwild et al., "High-Avidity Human IgGK Monoclonal Antibodies From a Novel Strain of Minilocus Transgenic Mice" <u>Nature Biotechnology</u> , 14(7):845-851 (Jul 1996) |
| *30 | Heid et al., "Real time quantitative PCR" <u>Genome Research</u> 6(10):986-994 (1996) |
| *31 | Hoogenboom and Winter, "By-Passing Immunisation: Human Antibodies from Synthetic Repertoires of Germline V _H Gene Segments Rearranged in Vitro" <u>J. Mol. Biol.</u> 227:381-388 (1992) |
| *32 | Hsieh, C.S. et al., "Development of Th1 CD4+ T Cells Through IL-12 Produced by Listeria-Induced Macrophages" <u>Science</u> 260:547-549 (1993) |
| *33 | Jenkins, M., "The Ups and Downs of T Cell Costimulation." <u>Immunity</u> , 1(6):443-446 (Sep 1994) |
| *34 | Jones et al., "Replacing the Complementarity-Determining Regions in a Human Antibody with those from a Mouse" <u>Nature</u> 321:522-525 (May 29, 1986) |
| *35 | June et al., "The B7 and CD28 Receptor Families." <u>Immunology Today</u> , 15(7):321-331 (Jul 1994) |
| *36 | Kaplan, M. H. et al., "Impaired IL-12 responses and enhanced development of Th2 cells in Stat4-deficient mice" <u>Nature</u> 382:174-177 (1996) |
| *37 | Kohler, G. and Milstein, C., "Continuous Cultures of Fused Cells Secreting Antibody of Predefined Specificity" <u>Nature</u> 256:495-497 (August 7, 1975) |
| *38 | Kuhn, R. et al., "Generation and analysis of interleukin-4 deficient mice" <u>Science</u> 254:707-710 (1991) |
| *39 | Kwon et al., "Manipulation of T Cell Costimulatory and Inhibitory Signals for Immunotherapy of Prostate Cancer." <u>Proc. Natl. Acad. Sci. USA</u> 94(15):8099-8103 (Jul 22, 1997) |
| *40 | Le Gros, G. et al., "Generation of Interleukin 4 (IL-4)-producing Cells In Vivo and In Vitro: IL-2 and IL-4 Are Required For In Vivo Generation of IL-4-producing Cells" <u>Journal of Experimental Medicine</u> 172:921-929 (1990) |
| *41 | Linsley and Ledbetter., "The Role of the CD28 Receptor During T Cell Responses to Antigen." <u>Annu. Rev. Immunol.</u> 11:191-212 (1993) |
| *42 | Lonberg and Huszar., "Human Antibodies From Transgenic Mice" <u>International Reviews of Immunology</u> 13(1):65-93 (1995) |
| *43 | Lonberg et al., "Antigen-Specific Human Antibodies From Mice Comprising Four Distinct Genetic Modifications" <u>Nature</u> , 368(6474):856-859 (Apr 28, 1994) |
| *44 | Lynch et al., "Flt3 Ligand Induces Tumor Regression and Antitumor Immune Responses In Vivo." <u>Nature Medicine</u> , 3(6):625-631 (Jun 1997) |
| *45 | Magram, J. et al., "IL-12-deficient mice are defective in IFN γ production and type 1 cytokine responses" <u>Immunity</u> 4:471-481 (1996) |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

NOV 05 2002

USCOMM-DC 80-398.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P1748R1E

Serial No.

10/088,950

Applicant

Frederic deSavauge et al.

Filing Date

20 Mar 2002

Group

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

*46	Marks et al., "By-Passing Immunization: Building High Affinity Human Antibodies by Chain Shuffling" <u>Bio/Technology</u> 10:779-783 (1992)
*47	Marks et al., "By-Passing Immunization: Human Antibodies From V-gene Libraries Displayed On Phage" <u>J. Mol. Biol.</u> 222:581-597 (1991)
*48	Melero et al., "Monoclonal Antibodies Against the 4-1BB T-cell Activation Molecule Eradicate Established Tumors." <u>Nature Medicine</u> 3(6):682-685 (Jun 1997)
*49	Morrison, S., "Immunology: Success in Specification" <u>Nature</u> 368(6474):812-813 (Apr 28, 1994)
*50	Neuberger, M., "Generating High-Avidity Human Mabs in Mice" <u>Nature Biotechnology</u> 14(7):826 (Jul 1996)
*51	Noben-Trauth, N. et al., "An interleukin 4 (IL-4)-independent pathway for CD4+ T cell IL-4 production is revealed in IL-4 receptor-deficient mice" <u>Proc. Natl. Acad. Sci. USA</u> 94:10838-10843 (1997)
*52	O'Garra, A., "Cytokines induce the development of functionally heterogeneous T helper cell subsets" <u>Immunity</u> 8:275-283 (1998)
*53	Presta, L., "Antibody Engineering" <u>Curr. Op. Struct. Biol.</u> 2:593-596 (1992)
*54	Riechmann et al., "Reshaping Human Antibodies for Therapy" <u>Nature</u> 332:323-327 (Mar 24, 1988)
*55	Romagnani, S. et al., "Human Th1 and Th2 cells: functional properties, mechanisms of development and role in diseases" <u>Allergologie</u> , Muenchen-Deisenhofen: Dustri Verlag Vol. 18(4):175-179 (1996)
*56	Schwartz, R., "Costimulation of T Lymphocytes: The Role of CD28, CTLA-4, and B7/BB1 in Interleukin-2 Production and Immunotherapy." <u>Cell</u> 71(7):1065-1068 (Dec 24, 1992)
*57	Seder, R.A. et al., "Interleukin 12 acts directly on CD4+ T cells to enhance priming for interferon γ production and diminishes interleukin 4 inhibition of such priming" <u>Proc. Natl. Acad. Sci. USA</u> 90:10188-10192 (1993)
*58	Shimoda, K. et al., "Lack of IL-4-induced Th2 response and IgE class switching in mice with disrupted Stat6 gene" <u>Nature</u> 380:630-633 (1996)
*59	Sprecher et al., "Cloning and Characterization of a Novel Class 1 Cytokine Receptor" <u>Biochem. & Biophys. Res. Comm.</u> 246:82-90 (1998)
*60	Swain et al., "Helper T-cell subsets: phenotype, function and the role of lymphokines in regulating their development" <u>Immunol. Rev.</u> 123:115-144 (1991)
*61	Thimmappaya et al., "Adenovirus VAI RNA is required for efficient translation of viral mRNAs at late times after infection" <u>Cell</u> 31(3 Pt 2):543-551 (Dec 1982)
*62	Umetsu and DeKruyff, "Th1 and Th2 CD4+ Cells in the Pathogenesis of Allergic Diseases" <u>Soc. Exp. Biol. Med.</u> 215:11-20 (1997)
*63	Urdal, D.L., "Cytokine Receptors" <u>Ann. Reports Med. Chem.</u> , Chapter 23, 26:221-228 (1991)
*64	Wells et al., "Cassette Mutagenesis: An Efficient Method for Generation of Multiple Mutations at Defined Sites" <u>Gene</u> 34(2-3):315-323 (1985)
*65	Wells et al., "Importance of Hydrogen-Bond Formation in Stabilizing the Transition State of Subtilisin" <u>Philos. Trans. Royal Soc. London Ser. A</u> 317:415-423 (1986)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED

NOV 05 2002

TECH CENTER 1600/2900

USCOMM-DC 80-398

Serial No.
10/088,950

(Use several sheets if necessary)

Filing Date
20 Mar 2002

Group

*66	Wu, C. et al., "Characterization of IL-12 receptor $\beta 1$ chain (IL-12R $\beta 1$)-deficient mice" <u>J. Immunol.</u> 159:1658-1665 (1997)
*67	Zoller and Smith., "Oligonucleotide-Directed Mutagenesis Using M13-Derived Vectors: An Efficient and General Procedure for the Production of Point Mutations in Any Fragment of DNA" <u>Nucl. Acids Res.</u> 10(20):6487-6500 (1982)

RECEIVED
NOV 05 2002
TECH CENTER 1600/2900

Date Considered

USCOMM-DC 80-398.